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10/553,929	08/29/2006	Patrick Leahy	KEL01 P-146	6150

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EXAMINER	
MCEVOY, THOMAS M	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,929	LEAHY, PATRICK	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8,11-19,21-24,27,28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,11-19,21-24,27,28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 6-8, 11-19, 23, 24, 27, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford et al. (US 2002/0143349).

Regarding claims 1, 11, 12, 24 and 27, Gifford et al. disclose a device for use in parietal surgery, the device comprising: a body 110; an implant 4B capable of residing in the peritoneum, the implant being locatable in a collapsed state (Figure 21) within the body, the parietal surgical implant being adapted to be displaceable between the collapsed state and an expanded state (Figure 22); means (110, 118, 126) for expanding the parietal surgical implant from the collapsed state into the expanded state; means 8 for retaining the parietal surgical implant within the body in the collapsed state, the retaining means comprising a sleeve 8 within which the parietal surgical implant is

locatable, the sleeve being displaceable relative to the parietal surgical implant in order to expose the parietal surgical implant; a mesh 116 adapted for use in repairing hernias (capable of use in repairing hernias), said mesh having a mesh perimeter (around hub 120) and a shaft mounting area 118 , the mesh being mounted to a shaft 122/126. Gifford et al. fail to explicitly disclose that the expanding means comprising a collar slidably mounted about the shaft. However, Gifford et al. disclose a plurality of arms (at 118, Figures 21-23) mounted concentrically around the shaft and concentrically within an arm mounting position of the mesh (evident from Figures 21-23). It would have been obvious to one of ordinary skill in the art to have used a collar to mount the arms concentrically around the shaft because one of ordinary skill in the art would recognize that this is one of the only possibly means for mounting these structures so that they are slidable together over shaft portion 126. Gifford et al. further disclose: the arm mounting position (portion of mesh around 118) being spaced apart from the shaft mounting area 120 (evident from Figures 21-23), the collar/arms (as modified above) being displaceable towards the mesh (towards a portion of the mesh - Figure 21 vs. 22), in order to urge the mesh towards the expanded state; Gifford et al. fail to explicitly disclose an abutment as claimed. It is evident from Figures 21-23 that hub 118 must be pressed over lock 124/shaft portion 122 (paragraph 0078) in order to expand the mesh and this would require some form of abutment. Gifford et al. disclose an abutment on shaft 10 in another embodiment (Figure 4) for a similar purpose. Therefore, it would have been obvious to one of ordinary skill in the art to have formed a blunt abutment on the end of shaft 110 as done for shaft 10 in order to press the hub forward and cause

expansion of the mesh. Furthermore, it would have been obvious to one of ordinary skill in the art to have provided disk 144 to the end of 110 and integral with the abutment in order to seal off the neck of the aneurysm after the mesh is separated so that hot fluid can be slowly released into the blood stream as/after the aneurysm is shrunk by tilting the disc (Figure 26; paragraphs 0091 and 0093; Gifford et al. suggest using the disc on other embodiments). With this modification the mesh would be seated against the abutment once separated from the shaft which would at least partially secure the mesh in place. The abutment has a recess (formed by the cup shape of the disc – Figure 26) within which a cut end of the shaft may/could be seated, such that the abutment covers the cut end of the shaft and distributes the pressure exerted by the cut end of the shaft. Examiner notes that since the disc and mesh must occupy the same space within the neck - see Figures 19 and 26 - the cut end of 122 would sit within the disc. **Regarding claims 6-8 and 16**, since the body 110 and shaft 126 must be moved relative to eachother to deploy the mesh, it would have been obvious to one of ordinary skill in the art to have provided a grip (which can be considered as an actuator) on the body and shaft at their proximal ends which are adjacent to eachother (Figure 1). **Regarding claims 13 and 15**, the mesh is spherical and substantially circular about its circumference and the shaft mounting area is located substantially centrally therein; and the plurality of arm mounting positions are circumferentially spaced apart-on the mesh perimeter (evident from Figures 21-23). **Regarding claim 14**, the arm mounting position is located adjacent the mesh perimeter (evident from Figures 21-23). **Regarding claim 17**, the mesh is separable from the shaft portion 126 (as Applicant's

mesh is separable from a portion of the shaft 38 but remains attached to another portion). **Regarding claim 18**, the mesh and the shaft are adapted for a press fit engagement via lock 124. **Regarding claim 19**, it is well-known in the art to form catheter shafts such as catheter 126 from polymeric materials which are soft enough (such as PTFE) to be cut by conventional surgical equipment. Therefore, it would have been obvious to one of ordinary skill in the art to have formed shaft 110 from such a material. **Regarding claim 23**, it would have been obvious to one of ordinary skill in the art to have formed at least a proximal section of the implant with a polyamide coating to protect the neck of the aneurysm and adjacent vessels from energy transmission as the coating does in other embodiments (paragraph 0068). **Regarding claims 28 and 30**, Gifford et al. disclose the method as claimed; the individual steps addressed above. The collapsed implant must be delivered through an incision based on Figure 1 since there is no natural body opening at the insertion site shown. As explained above, before the incision is closed - but not after the incision is closed, the abutment is located against the mesh. **Regarding claim 31**, the body 110 is elongated and tubular as evident from Figures 21-23.

4. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford et al. (US 2002/0143349) in view of Murphy et al. (US 2003/0171739).

Regarding claims 21 and 22, Gifford et al. disclose the device as described above but fail to disclose a distensible member as claimed. Murphy et al. disclose an inflatable balloon on a catheter which slows blood flow in order to help deploy an implant of similar function to that of Gifford et al. (paragraph 0072 of Murphy et al.).

Therefore, it would have been obvious to one of ordinary skill in the art in view of Murphy et al. to have provided an inflatable balloon on the body of the Gifford et al. device to slow blood flow in order to help deploy the implant.

Response to Arguments

5. Applicant's arguments filed December 14th 2010 have been fully considered but they are not persuasive. Applicant has argued that the implant of Gifford et al. is incapable of use in repairing hernias due to its size. The implant has a similar structure to Applicant's device and others in the hernia repair art (see attached References Cited). Applicant has not provided any evidence that its size renders it incapable of this use. Applicant has argued that Gifford et al. is non-analogous art and should not be used in an obviousness rejection. Paragraphs 0042-0044 of Applicant's pre-grant publication are evidence that one of ordinary skill in the art in Applicant's field of endeavor would be well aware of any surgical implant that could occlude a wound when considering the instant invention. The implant of Gifford et al. meets this criterion. Applicant has argued that it would be hindsight reasoning to combine the various features within Gifford et al. as proposed above. The combined features are either intended to be combined or would clearly benefit the functioning of the Gifford et al. device. Providing a blunt end as in Figure 4 to the Figure 21-23 embodiment would clearly aid in deploying the implant. Otherwise, all the axial force of deployment would be directed between members 118 and the narrow thickness of the catheter end. Applicant has argued that there is no cut end in the Figure 21-23 embodiment. It is not clear what structural difference a cut end would have over the end of tube 122.

Applicant has argued that the abutment of Gifford et al. does not secure the implant in place as claimed. The claims do not require a permanent or fixed relationship between the abutment and implant and do not define over a structure which simply abuts the implant within a recess; even in a transitory or temporary manner. Examiner appreciatively notes Applicant's genuine attempt to advance prosecution by claiming the invention in a detailed manner. However, additional structural limitations are believed to be necessary in order to define over the prior art of record. Therefore, the rejection is respectfully maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS MCEVOY whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/
Examiner, Art Unit 3731

/Gary Jackson/
Supervisory Patent Examiner, Art Unit